No. 16-493

IN THE
# Supreme Court of the United States

MERCK & CIE, ET AL.,
*Petitioners,*

v.

WATSON LABORATORIES, INC.,
*Respondent.*

On Petition for a Writ of Certiorari
to the United States Court of Appeals
for the Federal Circuit

## BRIEF FOR THE RESPONDENT IN OPPOSITION


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## QUESTIONS PRESENTED

Until being substantively rewritten in 2011, the Patent Act barred an inventor from obtaining a patent if "the invention was … in public use or on sale in this country, more than one year prior to the date of the application" for the patent. 35 U.S.C. § 102(b) (2006). It is undisputed that a product is "on sale" if offered for sale, whether or not a sale is completed. The on-sale bar prevents inventors from extending their 20-year monopoly by delaying the filing of their patent applications even after the invention is ready for patenting.

In this case, two years before filing its patent application, patent owner Merck offered for sale enough of its drug product to make 62.5 million doses.

The questions presented are:

1. Whether a confidential offer for sale is still treated as an offer for sale, so that an inventor cannot circumvent the on-sale bar and extend his patent monopoly by the simple expedient of having purchasers sign confidentiality agreements.

2. Whether petitioners forfeited their argument that Merck's confidentiality agreement avoids the on-sale bar, because petitioners did not present that argument below, and the lower courts therefore did not address it.

## RULE 29.6 STATEMENT

Watson Laboratories, Inc. is a wholly owned subsidiary of Actavis Holdco US, Inc., and an indirect subsidiary of the following entities: Teva Pharmaceuticals USA, Inc.; Orvet UK; Teva Pharmaceutical Holdings Coöperatieve U.A.; IVAX LLC; Teva Pharmaceuticals Europe B.V.; and Teva Pharmaceutial Industries, Ltd., a publicly traded company. No other publicly traded company owns 10% or more of Watson's stock.

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## BRIEF FOR THE RESPONDENT IN OPPOSITION

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Petitioners seek to present a question about whether a *secret* offer to sell implicates the statutory "on-sale bar" to obtaining a patent. But that is not the question petitioners litigated below. Unsurprisingly, then, neither the district court nor the Federal Circuit ever addressed that question. Indeed, the fundamental premise of the petition for certiorari—that Merck's 1998 offer to sell 62.5 million doses of its product was secret, not public—was never the basis of factual findings below, or even any discovery. To the extent there is evidence in the record on the issue of confidentiality, it actually *undermines* petitioners' claim that their offer was a secret one. Petitioners' question therefore is neither preserved nor properly presented by this case. That is reason enough to deny the petition.

The question presented does not warrant review in any event. Petitioners, Merck and Bayer, contend that small inventors need a narrower on-sale bar that will not prevent startups from signing manufacturing and supply agreements with larger companies. But the Federal Circuit has already adopted just such an interpretation. In *The Medicines Company v. Hospira, Inc.*, 827 F.3d 1363 (Fed. Cir. 2016), the en banc Federal Circuit unanimously ruled *for the patentee*, adopting reasoning that will allow small inventors to execute manufacturing and supply agreements without triggering the on-sale bar. Petitioners are simply incorrect in describing *Medicines Company* as "reject[ing] the United States' request to

correct course," Pet. 3. *Medicines Company* held, in fact, that the confidentiality of an agreement is a factor in analyzing whether the agreement triggers the on-sale bar. *Id.* at 1376. The Federal Circuit's unanimous reformulation of its own precedent has not yet had time to percolate, and its significance is declining in any event, because the statute at issue here and in *Medicines Company* was amended in 2011.

Petitioners are not satisfied with *Medicines Company* because their actual interests have nothing to do with the on-sale bar's effect on startup inventors and their suppliers. Petitioners are, after all, among the largest pharmaceutical companies in the world, and there is no dispute that petitioners themselves manufactured the 62.5 million doses they offered to sell in this case. Petitioners' argument—that confidential sales *never* trigger the on-sale bar—would allow inventors to begin commercializing their products well before applying for patent protection, simply by using confidentiality agreements to keep their sales quiet. But the on-sale bar was adopted to prevent precisely this tactic, which would allow a patentee to "preserve[] the monopoly to himself for a longer period than is allowed by the policy of the law." *City of Elizabeth v. Pavement Co.*, 97 U.S. 126, 136-37 (1878).

Accordingly, even if the question were properly presented, there would be no reason for this Court to review the Federal Circuit's interpretation of the pre-2011 statute. There certainly is no reason to rush forward with review just months after *Medicines Company*, or to do so in a case where the question presented was not raised until after the court of ap-

peals' decision, and that raises none of the policy concerns petitioners identify.

The petition for certiorari should be denied.

## STATEMENT

### A. The On-Sale Bar Prevents Inventors From Extending The Patent Monopoly By Commercializing Their Invention Years Before Applying For A Patent

Under the Patent Act as it stood before the 2011 amendment, an inventor was not entitled to a patent if "the invention was … in public use *or on sale* in this country[] more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102(b) (2006) (emphasis added). As this Court has recognized for over a century, this on-sale bar ensures that an inventor cannot effectively extend its patent monopoly by beginning commercial exploitation of an invention but then waiting to apply for a patent. *See City of Elizabeth*, 97 U.S. at 136-37 (noting that "an inventor acquires an undue advantage over the public by delaying to take out a patent, inasmuch as he thereby preserves the monopoly to himself for a longer period than is allowed by the policy of the law"); *see also Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1, 13 (1829).

Given this goal, this Court has unsurprisingly read the on-sale bar to ask whether the product has been "the subject of a *commercial* offer for sale." *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 67 (1998) (emphasis added). When an inventor acts to commercialize an invention that is ready for patenting, but

does not seek a patent within one year, the inventor triggers the on-sale bar. *Id.*

### B. Petitioners Litigated This Case On The Theory That Merck Had Made No Offer Of Sale, Not That It Had Made A Secret Offer

At trial and on appeal, petitioners raised only one issue concerning the on-sale bar: whether Merck's correspondence with a potential customer in 1998 constituted an actual offer to sell the product. The Federal Circuit ruled against petitioners, concluding that Merck had offered to sell a commercial quantity of the patented product—enough to make 62.5 million doses—nearly two years before Merck applied for a patent. It was not until after the Federal Circuit's decision that petitioners first argued, in a rehearing petition, that Merck's offer did not trigger the on-sale bar because it was purportedly secret, not "public."

1. The patent at issue in this case, U.S. Patent No. 6,441,168 (the '168 patent), is directed to a crystalline calcium salt of a tetrahydrofolic acid ("MTHF"). The application for the '168 patent was filed on April 17, 2000. Pet. App. 2a.

In 1997, three years before Merck applied for the '168 patent, Merck and Weider Nutrition International, Inc. ("Weider") began exploring a strategic partnership to introduce dietary supplements with Merck ingredients into the United States. Pet. App. 2a. The first major potential project was a joint venture to market and distribute MTHF. *Id.* From the outset, Weider made clear that it was "interested in

putting together a product containing [MTHF]." C.A. App. 1367.

In connection with those discussions, Merck and Weider executed a Confidentiality and Noncompetition Agreement (the "Merck-Weider Agreement") in February 1998. Pet. App. 2a. That Agreement restricted the parties' disclosure of shared "Confidential Information." But the provision of the Merck-Weider Agreement on which petitioners relied throughout this case, Section 5.2, had nothing to do with confidentiality. It provided: "Unless and until such definitive agreement regarding a transaction between Weider and Merck has been signed by both parties, neither party will be under any legal obligation of any kind with respect to such a transaction." *Id.* at 25a.

In August 1998, Weider notified Merck that it was no longer interested in forming a joint venture to market MTHF in the United States, but stated that it would like to purchase two kilograms of MTHF, equivalent to 62.5 million doses, on a stand-alone basis. *Id.* at 2a-3a, 14a-15a. A manager at Merck responded, in a signed fax, asking Weider to send its MTHF purchase order to him directly and explaining that he would "arrange everything." *Id.* at 3a, 8a. He provided a price, wrote that payment terms were "60 days net," and explained that the product would be delivered, free of charge, to Weider's U.S. facility. *Id.* Merck even informed Weider that if it wanted more MTHF, Merck had "no problem … immediately" delivering additional quantities. *Id.* After more communication between the companies, on October 8, 1998, Merck sent Weider a letter confirming that

it had placed a "first order" for two kilograms of MTHF. *Id.* at 4a.

Merck and Weirder eventually decided not to go through with the deal. Merck had begun trying to sell MTHF to a Weider competitor named Whitehall Robins ("Whitehall"). Whitehall informed Merck that it was interested in obtaining exclusive rights to market MTHF in the United States and Canada. *Id.* And Weider ultimately decided to cancel its order. *Id.* at 4a-5a. On January 9, 1999, Weider emailed Merck and noted that the parties had made a "mutual decision" to cancel Weider's "existing order for [MTHF]." *Id.* (brackets in original).

2. Petitioners sued Watson for infringing claim 4 of the '168 patent. As relevant here, Watson defended on the ground that claim 4 is invalid under the on-sale bar because Merck offered MTHF for sale in 1998. The dispute in the district court centered entirely on whether Merck's communication to Weider was an offer; Merck never argued that the on-sale bar did not apply because its offer was secret, not "public."

Before the district court, petitioners did not invoke any confidentiality-related provision of the Merck-Weider Agreement. Petitioners instead relied on Section 5.2, arguing primarily that, under this provision, "there was no commercial sale or offer for sale." Pet. App. 27a. The district court agreed with petitioners: it held that there was no commercial offer, because under Section 5.2 there could be no "legally binding sale until reduced to writing and signed by both parties," and so Merck's correspondence to Weider "was also not an offer that could be made binding upon acceptance." Pet. App. 29a-30a. The district

court also agreed with petitioners that there was no offer because "industry-standard terms," like "liability apportionment," "were missing from the communications." Pet. App. 30a.

Watson appealed the holding that there was no "commercial offer or sale of MTHF" that triggered the on-sale bar. Pet. App. 30a. In their brief to the Federal Circuit, petitioners focused entirely on the same grounds on which the district court decided the case: whether Merck's offer to sell was an offer at all, under industry practice or under the Merck-Weider Agreement.

3. The Federal Circuit reversed. Pet. App. 2a. The court first concluded that Merck's fax to Weider "contained all the required elements to qualify as a commercial offer for sale." Pet. App. 8a. And "in the weeks following [Merck's] fax both Merck and Weider proceeded on the understanding that Merck had made an unequivocal offer to sell MTHF." Pet. App. 9a.

The court also rejected petitioners' reliance on Section 5.2 of the Merck-Weider Agreement. The Court noted that petitioners "point[ed] to nothing in that agreement indicating that it was intended to have any applicability to a stand-alone product purchase." Pet. App. 13a. But "[e]ven assuming *arguendo* … that the [Merck-Weider] Agreement can be stretched to cover a standalone purchase of MTHF," the court of appeals wrote, "it does not help [petitioners]," because Section 5.2 does not require that "an offer for sale and a completed sales agreement … be contained in the same document." Pet. App. 13a-14a. Thus, even if the offer could not become a sales

agreement upon Weider's signature, it was still "a commercial offer to sell MTHF." *Id.*

The court of appeals noted two issues *not* raised by this case. First, the court acknowledged that the en banc court was then considering, in *Medicines Company*, "whether an inventor's agreement with another party to manufacture the inventor's products is sufficient to trigger the on-sale bar," but explained that this case was different because here "*there is no dispute* that the bar arises when a product is marketed to the public prior to the critical date." Pet. App. 15a n.4 (emphasis added).[1] Second, the court noted that Merck's offer to sell MTHF was not "for experimental purposes," but for "commercial exploitation." Pet. App. 14a-15a.

4. After the Federal Circuit's decision, petitioners filed a petition for rehearing changing their theory. They contended, for the first time, that the on-sale bar did not apply because the offer was not a public one. The court of appeals denied rehearing and the requested stay of mandate. Pet. App. 41a-42a.

5. Petitioners then applied to the Chief Justice for a stay of the court of appeals' mandate pending the filing and disposition of a petition for a writ of certiorari. The Chief Justice denied the stay application. No. 16A74.

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[1] Petitioners had filed a Rule 28(j) supplemental-authority letter noting the government's brief in *Medicines Company* and asking that this case be held pending the en banc court's disposition.

### C. In A Separate En Banc Decision, The Federal Circuit Narrowly Interpreted The Pre-2011 On-Sale Bar And Held, Consistent With The Position Of The United States, That An Inventor's Supplier Agreement Did Not Trigger The Bar

Because the question petitioners present for this Court's review has never been raised in this case, petitioners focus their petition on the Federal Circuit's recent en banc decision in *Medicines Company*, and on an amicus brief the United States filed in that case. Unlike this case, *Medicines Company* concerned a small inventor's ability to contract with larger companies to carry out manufacturing without triggering the on-sale bar. Here, by contrast, Merck itself manufactured the 62.5 million doses of MTHF it tried to sell to Weider.

The petition misleadingly suggests that *Medicines Company* adopted an expansive interpretation of the pre-2011 on-sale bar, conflicting with the position of the United States and making it impossible for small companies to enter manufacturing agreements. *E.g.*, Pet. 3-4. In reality, the opposite is true: the Federal Circuit substantially *agreed* with the United States and ruled for the *patentee*, adopting a standard that places significant weight on the confidentiality of the transactions and will allow small inventors to enter into supplier agreements without triggering the on-sale bar.

1. Medicines Company is a specialty pharmaceutical company that does not have its own manufacturing facilities and is not capable of making its products in-house. 827 F.3d at 1366-67. It therefore

contracted with a third-party provider to manufacture commercial quantities of a product for which it ultimately sought patent protection. *Id.* When Medicines Company later sought to enforce the patent, the defendant claimed the manufacturing contract triggered the on-sale bar.

2. A panel of the Federal Circuit held that Medicines Company's contract with its manufacturer did trigger the on-sale bar. *Id.* at 1369-70. The panel reasoned that because Medicines Company paid the manufacturer for services that resulted in the patented product, the transactions were commercial sales of the product. *Id.* at 1369. A contrary conclusion, according to the panel, would have conflicted with the Federal Circuit's prior conclusion that there is no "supplier exception" to the on-sale bar—*i.e.*, that a contract between a patentee and its supplier is not categorically excluded from the on-sale bar. *Id.* at 1369-70 (citing *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353, 1355 (Fed. Cir. 2001)).

2. The Federal Circuit agreed to rehear the case en banc. It ordered briefing concerning whether the on-sale bar was triggered by Medicines Company's manufacturing contract, and whether the court should create a "supplier exception" to the on-sale bar. 827 F.3d at 1370.

3. The government filed an amicus brief before the en banc court in support of Medicines Company. *See* En Banc Brief for the United States as *Amicus Curiae*, *Medicines Co. v. Hospira, Inc.*, Nos. 14-1469, -1504, ECF No. 132 (Fed. Cir. filed Mar. 2, 2016) ("U.S. *Medicines Co.* Br."). The government focused on one key theme: "Many startup companies and small-scale inventors are unable to produce their in-

ventions in-house," and "when an inventor contracts confidentially with a third party to manufacture the invention on its behalf, that transaction may not make the invention available to the public any more than a large company's confidential in-house manufacturing does." *Id.* at 2-3; *see also id.* at 4 ("The question presented is whether the on-sale bar applies where an inventor confidentially contracts with a third-party manufacturer to produce the invention for later sale by the inventor to the public.").

The government proposed two legal theories to support its position. First, where the patented invention is a product, "the traditional hallmark of a sale is the transfer of title." *Id.* at 1. Because Medicines Company retained title to the drug product while its supplier manufactured it, the government argued that the drug product was "never the subject of a commercial sale or offer for sale" as part of the manufacturing contract. *Id.*

Second, the government argued that a product is "on sale" only if it is "available to interested members of the public." *Id.* at 13. The government emphasized, though, that an offer for sale is public even if it is not "broadcast to the public at large," but is instead limited to a "single company that wanted to purchase the invention." *Id.* at 13-14. The government advocated for a multi-factor inquiry as to whether a product is "on sale," similar to the inquiry the Federal Circuit uses to determine whether a product is "in public use" under another provision of the same statute. *Id.* at 14-15. The government argued that Medicines Company's invention "was never made available for sale to the public," or any interested member of the public, because its transac-

tions with its manufacturer "were confidential and exclusive, such that no member of the public could have purchased the drug product from [the manufacturer]." *Id.*

4. The en banc Federal Circuit unanimously ruled for the patentee and held, contrary to the panel's decision, that Medicines Company's manufacturing contract did not trigger the on-sale bar. That clarified analysis, the court stated, was "not inconsistent" with the holding of any prior Federal Circuit case; to avoid "any doubt," any loose language to the contrary in earlier cases was "overruled." 827 F.3d at 1380. The court's clarified approach was substantially consistent with the government's.

Consistent with the purpose of the on-sale bar—to prevent inventors from extending their patent monopoly by beginning commercial exploitation well before applying for a patent—the Federal Circuit held that for a product to be "on sale" it must be "commercially marketed." 827 F.3d at 1373. It held that "in most instances," the absence of title transfer will indicate that the product was not "on sale"; the court did not create a bright-line rule out of concern that such a rule could cause problems in the context of method patents and software licenses. *Id.* at 1376.

Similarly, the court held that the "confidential status of the transactions" generally demonstrates that a product is not "on sale." *Id.* The court again did not create a bright-line rule, recognizing that in some cases—such as classified military contracts—the fact that the contract was secret did not diminish the fact that the product was being commercially exploited and hence "on sale." *Id.* (citing, *e.g.*, *Hobbs v. U.S. Atomic Energy Comm'n*, 451 F.2d 849, 860 (5th Cir.

1971) (confidential contract for sale to government of valves used in the Manhattan Project triggered on-sale bar)).

The en banc court's decision was limited to the pre-2011 version of the statute. The court recognized that in 2011, Congress had amended the on-sale bar in a number of ways, and that amici had argued that the new text limits "on sale" to public sales. *Id*. at 1380 n.3; *see* Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 3(b)(1), 125 Stat. 285-86 (2011) (codified at 35 U.S.C. § 102(a)(1) (2012)).[2] The en banc court left open the question whether the on-sale bar in the *amended* statute turns on the "public" nature of a particular sale. *Id*. at 1380 n.3. That question is currently pending before the Federal Circuit. *See, e.g.*, *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*, Fed. Cir. No. 16-1284.

## REASONS FOR DENYING THE WRIT

### I. The Federal Circuit's Conclusion That Merck's Offer To Sell 62 Million Doses Triggered The On-Sale Bar Does Not Warrant Review

#### A. Merck Relies On A Theory It Failed To Raise Until After Oral Argument At The Federal Circuit

This Court "do[es] not decide in the first instance issues not decided below." *NCAA v. Smith*, 525 U.S. 459, 470 (1999). That is especially true of issues that were not even *argued* below. *See, e.g.*, *United States*

[2] The 2011 amendment applies to patents for which the application was filed after the effective date of the statute. *See* America Invents Act § 3(n), 125 Stat. 293.

*v. United Foods, Inc.*, 533 U.S. 405, 417 (2001) (refusing "to allow a petitioner to assert new substantive arguments attacking … the judgment when those arguments were not pressed in the court whose opinion we are reviewing"); *FW/PBS, Inc. v. City of Dallas*, 493 U.S. 215, 237 (1990) (refusing to consider issues that "were not pressed or passed upon below").

Petitioners' sole question presented—whether the on-sale bar "applies only to sales or offers of sale made available to the public," Pet. i—was *neither* presented *nor* passed upon below. The Federal Circuit's opinion spoke to whether Merck's fax was in fact an offer for sale, and whether that offer was required to (and did) comply with a provision of the Merck-Weider Agreement requiring a signed writing for any transaction between Merck and Weider. The district court likewise addressed only whether the fax qualified as an offer for sale, as well as other invalidity defenses that are indisputably irrelevant here. Neither court asked or decided whether the fax was an offer for *public* sale.

The lower courts never addressed that issue because petitioners did not raise it. Petitioners did not argue to the district court or to the Federal Circuit (either in briefing or at oral argument) that any offer or sale between Merck and Weider was not public and therefore not invalidating. Petitioners first mentioned (but did not adopt) this argument in a post-oral argument letter to the Federal Circuit, referencing the United States *amicus* brief in *Medicines Company* and asking that the case be held. But a supplemental-authority letter can only amplify on an argument in "the brief" or "a point argued orally." Fed. R. App. P. 28(j). When such a "letter present[s]

new argument, it [is] improper." *Hall v. Shinseki*, 717 F.3d 1369, 1373 n.4 (Fed. Cir. 2013); *see also Desper Prods, Inc. v. Qsound Labs., Inc.*, 157 F.3d 1325, 1335 (Fed. Cir. 1998).

Petitioners first purported to adopt their public-sale argument in a petition for rehearing, but a rehearing petition is too late to preserve an argument not previously pressed or passed on. *See Haas v. Peake*, 544 F.3d 1306, 1308 (Fed. Cir. 2008) ("[A] party may not raise new and additional matters for the first time in a petition for rehearing" (citation omitted)); *see also Chaidez v. United States*, 133 S. Ct. 1103, 1113 n.16 (2013) (refusing to consider argument that petitioner did not "adequately raise … in the lower courts" because it was first raised, if at all, in a "petition for rehearing en banc in the Seventh Circuit"); *cf. Adams v. Robertson*, 520 U.S. 83, 89 n.3 (1997).

Petitioners do not contend that they properly raised their public-sale argument below, nor do they contend that the lower courts addressed that argument. Instead, they simply assert that they did not have to raise such an argument because it would have been "futile" under (unspecified) Federal Circuit precedents. Pet. 7. But in the case from this Court that petitioners cite, the party *did* preserve the "futile" argument in the court of appeals by giving it "a few pages of its appellate brief." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 125 (2007). Here, by contrast, petitioners failed to say anything. And that failure matters.

First, petitioners not only failed to argue below that a non-public offer or sale *never* triggers the categorical bar, they failed to even argue that the purported-

ly non-public nature of their offer was *relevant* to the on-sale bar analysis *at all*. Under the Federal Circuit's approach that petitioners now contest, "the confidential nature of the transactions is a factor which weighs against the conclusion that the transactions were commercial in nature," and hence triggered the on-sale bar. *Medicines Co.*, 827 F.3d at 1376. The en banc court deemed that holding to be consistent with its prior precedent. *See id.* at 1380. Petitioners, however, argued only that they never made an offer, not that any offer was confidential. As a result, when they asked that the case be held for *Medicines Company*, the panel saw no reason to do so. *See* Pet. App. 15a n.4.

Second, petitioners' failure to raise this issue precluded the necessary factual development. Thus, in this case, there was no discovery and were no factual findings concerning whether Merck's offer and sale of MTHF were, in fact, secret. The Federal Circuit expressed its skepticism that the Merck-Weider Agreement (the basis for petitioners' claim of confidentiality) even applied to "a stand-alone product purchase" after the parties abandoned their joint venture. Pet. App. 13a. As discussed below, even the limited confidentiality-related evidence in the record suggests that there was nothing secret about Merck's sale of 62.5 million doses to Weider. And there is ample reason to doubt the completeness of the record. Petitioners redacted all references to Weider from the documents they produced (purportedly on relevance grounds), and they completely withheld the invalidating offer and associated documents from their production even though they were indisputably responsive. Only after Watson learned of the documents' existence through third-party dis-

covery did Merck admit it had those documents and produce them.[3] Petitioners should not be allowed to further manipulate the fact-development process by claiming, at the eleventh hour and on an inadequate record, that its offer for sale was actually a secret one.

Because the sole issue presented for review to this Court was neither raised to nor addressed by the lower courts, this Court should deny certiorari.

### B. The Agreed-Upon Sale To Weider Likely Would Have Been "Public" Under Petitioners' Own Theory

The premise of petitioners' argument is that an invention can be sold commercially, but nevertheless not qualify as "on sale," if the seller keeps the offer confidential. Because petitioners never made the secret or public nature of Merck's offer an issue in the case, there was no factual development below concerning the extent to which the offer was public. To the extent the record addresses this issue, it suggests that there was nothing confidential about Merck's contemplated sale of more than 62 million doses of its product.

The petition repeatedly assumes that all that matters is that the *offer* be confidential. Indeed, petitioners repeatedly—and wrongly—conflate a *public offer*, a *public sale*, and being "on sale" *to the public*. *See infra* pp. 24-25 (discussing the single private sale

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[3] *See generally* Watson Mem. in Supp. of Mot. to Award Attorneys' Fees, No. 1:13-cv-978, ECF No. 131 (D. Del. filed Aug. 18, 2016). Watson's motion for attorneys' fees based on petitioners' discovery misconduct is currently pending at the district court, which held a hearing on November 2, 2016.

that invalidated the patent in *Pfaff*). The court of appeals expressly refrained from deciding whether the Merck-Weider Agreement applied to the negotiations at all. Pet. App. 13a. But even if it did, there is no indication that it would have made the *sale* confidential.

Quite simply, this was not a secret or restricted sale. By the time of the sale, Merck and Weider had already terminated their plans to market as a joint venture. Weider was no differently situated than any other member of the public. Indeed, the Merck-Weider Agreement did not restrain Weider from doing what it plainly planned to do: sell the MTHF from Merck commercially. The 2 kg that Weider agreed to buy would make 62.5 million doses. Merck was fully aware and in agreement that Weider intended to use some of the 62.5 million doses in dietary supplement products that Weider would sell to the public. As Merck confirmed in a December 16, 1998 memorandum, "Weider will initially try and launch L-5MTHF as a standalone product." C.A. App. 1387.

Petitioners identify *nothing* in the record suggesting that the sale would have been "confidential," such that Weider could not have re-sold the doses it bought from Merck to the public and advertised them as such. Petitioners misleadingly describe the district court's conclusion that the parties' "confidentiality agreement covered these discussions," Pet. 13-14, as if that meant that any *sale* would have been secret.[4] But while the Merck-Weider Agreement re-

[4] Petitioners also emphasize that Watson did not appeal that conclusion, but notably, the court of appeals expressed skepticism about it and accepted it only *arguendo*. *See* Pet. App. 13a.

stricted the parties' use of "Confidential Information" in *negotiating* the transactions, nothing in that Agreement suggests that the sale the parties were negotiating was intended to be a secret one. *See* C.A. App. 1477-82. And an offer to sell the invention to a member of the public, free and clear, places the invention "on sale" whether or not the offer is *communicated* publicly or privately. Most offers to sell goods and services, after all, are communicated in a private conversation, phone call, letter, or e-mail, rather than in a public marketplace. In *Pfaff*, for example, the invalidating purchase order was communicated orally and in writing, not publicly. *See* 525 U.S. at 58.

Finally, the record shows that an important reason Merck and Weider canceled Merck's sale of MTHF was that Merck was considering selling MTHF to a different company, Whitehall, instead. According to the Federal Circuit, "Whitehall informed Merck that it was interested in obtaining exclusive rights to market MTHF in the United States in Canada." Pet. App. 4a. Merck's interactions with Whitehall strongly suggest that Merck was actively shopping MTHF. The precise facts concerning these interactions, of course, were not developed because petitioners never made confidentiality an issue. But the facts in the record concerning Whitehall support the notion that there was nothing secret about Merck's offer to sell MTHF or its contemplated sale.

### C. Merck's Sale Of Its Own Product Does Not Raise The Small-Company Outsourcing Concerns Petitioners Invoke

Petitioners claim the question presented is important because the Federal Circuit's current law

"jeopardizes critical supply-chain transactions and threatens disparate treatment among market participants." Pet. 18. The "disparate treatment" with which petitioners claim to be concerned is that large companies can "both create their invention and prepare it for market without allowing their idea to spread beyond the parking lot," while smaller companies "may need to outsource testing, manufacturing, or marketing to a third party." *Id.* This case, of course, does not involve such a small company or such a supplier transaction, and those considerations do not justify review in any event.

*Medicines Company* recently considered this question en banc and unanimously clarified the scope of the pre-2011 on-sale bar to address these precise concerns. That decision—which directed courts to focus both on whether there was a title transfer and whether the transaction was confidential—concluded that the supplier relationship in that case did not trigger the on-sale bar. Indeed the Court implied that supplier relationships could only trigger the on-sale bar in unusual circumstances. 827 F.3d at 1380.

Petitioners argue that the Federal Circuit did not go far enough, and that the court should have held that secrecy alone should be dispositive. Petitioners' rule may be necessary to save their patent given that Merck's attempt to commercially exploit MTHF had nothing to do with any supplier agreement. But petitioners do not explain why the Federal Circuit's approach in *Medicines Company* does not adequately deal with the policy considerations petitioners invoke.

Merck's sale at issue in this case bears no resemblance to that of a small company relying on supplier

agreements for manufacturing. Merck—a major multinational pharmaceutical company—manufactured the invention itself, and then sold it to Weider so that Weider could commercialize it—*i.e.*, sell it to the public. Merck did not agree to *buy* manufacturing services, as in *Medicines Company*; it agreed to *sell* the patented invention to Weider, free and clear. Allowing a company like Merck to avoid the on-sale bar simply by committing its customer to secrecy, or by communicating its offer in private, would allow inventors to do precisely what the on-sale bar is intended to prevent—artificially extending the patent monopoly by commercially exploiting an invention for years before applying for a patent.

At a minimum, petitioners' claim that *Medicines Company* is insufficient to protect small companies is premature, especially given that the decision narrowed the on-sale bar to protect the very interests petitioners purport to invoke. The issue should be allowed to percolate for more than a few months before this Court deems it certworthy.[5]

### D. This Case Involves The Pre-2011 Version Of The Statute, And The Meaning Of The Revised Provision Is Currently Before The Federal Circuit

This case also involves the *pre-2011* version of the statute, before Congress amended it in the America Invents Act of 2011. The statute now prohibits issuance of a patent if "the claimed invention was … in

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[5] Despite petitioners' insistence on the dire consequences of the Federal Circuit's *Medicines Company* decision, not a single *amicus* filed in support of the petition for certiorari. By contrast, eight *amici* filed in *Medicines Company*, including pharmaceutical and biotechnology trade associations.

public use, on sale, *or otherwise available to the public before the effective filing date of the claimed invention*." 35 U.S.C. § 102(a)(1) (emphasis added to show amendment). *Medicines Company*, like this case, interpreted the pre-2011 version of the statute, and the Federal Circuit specifically left open the possibility that it would read the post-2011 version differently. 827 F.3d at 1380 n.3. Indeed, the Federal Circuit is already considering whether the addition of the phrase "or otherwise available to the public" changed the law to require that an invalidating sale (or offer for sale) be public. *See Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*, Fed. Cir. No. 2016-1284 (argued October 4, 2016).

Far from denying the importance of this amendment, petitioners rely heavily on it, apparently on the belief that the amendment is probative of what a prior Congress meant. *See* Pet. 11. But when the meaning of a statute is not clear, an amendment only settles the meaning *going forward*, it does not ordinarily show what the statute *has always meant*. Just as often, the opposite is true. *See, e.g.*, *Graham County Soil, Water & Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280 (2010) (Congress amended statute to settle circuit split; this Court nonetheless construed the pre-amendment statute to mean the opposite of what the amended statute means). Indeed, the 2011 amendment unquestionably did materially change the on-sale bar's scope in certain ways—for instance, allowing foreign sales to invalidate a patent. But the changes do not apply retroactively. *See* note 2, *supra*.

All the amendment definitively shows is that the question of how to interpret the *pre*-amendment statute is of declining significance.

## II. The Federal Circuit's Interpretation Of The Pre-2011 On-Sale Bar Is Correct

Petitioners do not dispute that an invention is "on sale" if it is offered for sale; a completed sale is not required. Nor do petitioners dispute that a single offer to sell can be enough. Petitioners argue only that even though the pre-2011 version of § 102(b) made no mention of a *public* sale, this Court has interpreted the statute to require that a sale be public and the Federal Circuit has ignored this Court's holdings. Petitioners' argument lacks merit.

1. The plain language of pre-2011 § 102(b) used the word "public," but not in relation to the on-sale bar. A person cannot obtain a patent if:

> the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

35 U.S.C. §102(b) (2006). Thus, the statute required an invalidating "use" to be "public," but did *not* require invalidating "on sale" activity to be "public." Even before the Federal Circuit was created, the Fifth Circuit characterized as "unrealistic" an attempt "to construe the statute so that 'public' in the phrase 'in public use or on sale' modifies not only 'use' but also 'sale.'" *Hobbs*, 451 F.2d at 860. That is why a valve was "on sale" even when it was sold only secretly, to the Manhattan Project. *Id.*; *see Medicines Co.*, 827 F.3d at 1376 (citing *Hobbs*).

Petitioners' discussion of the statutory text only confirms this point. *See* Pet. 9-10. Petitioners quote a dictionary definition of "on sale" as "available to customers," but never explain why that definition does not include making a product available to customers who agree to negotiate their purchase under a confidentiality agreement. Merck, for instance, unquestionably made MTHF "available to customers"—it reached an agreement to sell MTHF to Weider. Petitioners also incorrectly seek help from 26 U.S.C. § 6802, which requires that the Treasury Secretary provide tax stamps to be "kept on sale … in [larger] post offices" and in "designated depositar[ies]." The intended public nature of the sale does not come from the phrase "on sale," but from the overall statutory context—most obviously, the fact that the stamps must be "on sale … *in all post offices*." The mere use of the phrase "on sale" in the statute would not forbid a postmaster from meeting a particular customer in the dead of night to sell a stamp confidentially. Nor does the use of "on sale" mean that confidential commercial sales do not trigger the Patent Act's on-sale bar.

2. This Court has never rejected the plain reading of the statute, and it certainly has never affirmatively held that invalidating sales or offers must be public. Petitioners pull a series of quotes from this Court's decisions out of context, but not one of those decisions even suggests that invalidating sales or offers must be "public," or that confidential sales are not really sales.

Petitioners largely ignore *Pfaff v. Wells Electronics*, 525 U.S. 55 (1998), this Court's most thorough, recent discussion of the on-sale bar, which supports the

Federal Circuit's decision in *Medicines Company*. This Court unanimously identified two conditions to satisfy the on-sale bar. The first, not controverted, was that "the product must be the subject of a *commercial* offer for sale," and not simply put to experimental use. *Id.* at 67 (emphasis added). The second condition was that the product must also be "ready for patenting," even if not yet reduced to practice. *Id.* Nowhere in these two conditions, or anywhere in its unanimous decision, did the Court even imply that an offer for sale must be "public" to be invalidating. Thus, under *Pfaff*, the touchstone is whether an offer or sale was *commercial*, not whether it was "public" or "confidential."

Indeed, it is far from clear that *Pfaff* involved a "public" sale or offer as petitioners appear to use the term. Texas Instruments asked Pfaff to develop a new type of socket, and he did so; the relevant sale occurred when he showed a sketch of his idea to Texas Instruments and the company agreed to order the sockets once they were made. *Id.* at 58. There is no indication whatsoever that Pfaff made his invention available on the open market, or to other members of the general public, at that time. But the single sale, to *a* member of the public, invalidated the patent.

Petitioners rely principally on two 19th-century decisions: *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1 (1829), and *City of Elizabeth v. Pavement Co.*, 97 U.S. 126 (1878). *Pennock* did not interpret the on-sale bar, which did not yet exist. Rather, the statute in *Pennock* prohibited patenting if an invention was "known or used before the application." *Id.* at 17. Petitioners contend (Pet. 10) that the on-sale bar enacted several years later codifies *Pennock*'s reference

to "public use, or [being] publicly sold for use," but Congress, unlike *Pennock*, did not repeat the word "public." And in *Pennock*, the Court used "public" use to mean lawful use by people other than the inventor or his assistants. *See* 27 U.S. (2 Pet.) at 18-19. Use outside the inventor's immediate circle (other than by a thief) would be invalidating. The Court never even suggested that a private, confidential sale of the invention to someone else would not result in "use[]."

*City of Elizabeth* is also of no help to petitioners. In *City of Elizabeth*, this Court broadly articulated the on-sale bar, without limiting it to "public" sales or offers: "Any attempt to use [the invention] for a profit, and not by way of experiment, for a longer period than two years before the application, would deprive the inventor of his right to a patent." 97 U.S. at 137; *accord Pfaff*, 525 U.S. at 65 (same). *City of Elizabeth* went on to establish the "experimental use" exception: the invention in that case plainly was not on sale, but it was being tested in a public roadway, so the defendant asserted that it was in "public use." The Court disagreed, because the inventor had kept control of it during the experiment. 97 U.S. at 135-36. The Court repeatedly used the inventor's control as the touchstone: the inventor "did not sell it, nor allow others to use it or sell it. He did not let it go beyond his control." *Id.* at 136. Of course, a private sale would have put the invention beyond the inventor's control, even if the sale was secret, and the Court did not suggest otherwise. To the contrary, it stated that "[a]ny attempt to use [the invention] for a profit, and not by way of experiment, for a longer period than two years [now one year] before the application, would deprive the inventor of

his right to a patent." *Id.* at 137; *accord Pfaff*, 525 U.S. at 66 (same).

The other cases petitioners cite are even less relevant. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 148 (1989), involved the extent of federal preemption of state patent-like laws, and did not interpret the on-sale bar. Though it noted that a "public sale" *does* bar federal patent protection, it never suggested that a secret or confidential sale did *not* trigger the on-sale bar. The rest of the cases (at 12) simply hold that when a sale *is* public, it triggers the on-sale bar—a point that no one could dispute.

3. Petitioners' rule also runs contrary to the purpose of the on-sale bar. Petitioners contend that inventors should be able not just to offer their invention, but to sell their invention, for as long as they like before patenting, so long as all the sales are secret. Petitioners suggest that shielding confidential offers and sales is appropriate because § 102(b) is solely aimed at preventing inventors from removing existing knowledge from public use. *E.g.*, Pet. 12.

But that is not the only policy objective of the on-sale bar: rather, the statute prevents inventors from preserving a monopoly "for a longer period than allowed by the policy of the law." *City of Elizabeth*, 97 U.S. at 136-37. An inventor can fine-tune as long as she likes, but once the invention is ready for patenting, she cannot start using her invention "for a profit" outside the grace period (which is currently one year). *Id.* at 137. Allowing inventors to circumvent the on-sale bar with non-disclosure agreements would remove the statutory incentive to seek a patent; many inventors could easily have their cake and eat it too, first selling their invention for private

use for as long as possible and later obtaining a full period of patent monopoly.

4. The amicus brief for the United States in *Medicines Company* does not suggest otherwise. The government brief expressly does *not* contend—as petitioners seem to be arguing here—"that [an] offer must be broadcast to the public at large." U.S. *Medicines Co.* Br. at 13. The government acknowledges that the single sale in *Pfaff* rules out any such reading. Rather, the government's approach asks whether a particular sale makes (or offer would make) the invention "available to interested members of the public." And on that question, the government endorses a multi-factor test drawn from this Court's decisions, *see id.* at 14-15 ("The Supreme Court has identified several factors as relevant to determining whether a use makes the invention publicly available . . . ."). Under the government's proposed test, an inventor could not avoid the on-sale bar by forcing customers to sign confidentiality agreements, because the test for whether a sale makes the invention "publicly available" looks at factors like "whether the use is mainly for the purposes of trade and profit, or to conduct the manufacturer's business," or whether "the inventor maintained control over the invention." *Id.* at 14 (internal quotation marks, alterations, and citations omitted).

Merck's sale to Weider so that Weider could commercialize the product was far from the type of confidential outsourcing of manufacturing the government, and the Federal Circuit in *Medicines Company*, saw as outside the scope of the pre-2011 on-sale bar. Thus, even if the government's amicus brief

were the law, petitioners cannot even claim they would win under it.

* * * * *

Petitioners ask this Court to grant review on a question they did not raise until after the court of appeals' decision. That alone is reason to deny the petition. But even if it were not, there is no reason for this Court to review the Federal Circuit's decision in *Medicines Company*. That decision correctly applies this Court's precedents, is consistent with the policy interests at the heart of the on-sale bar, addresses the concerns raised by the United States, and is of decreasing importance as it interprets an outdated version of the statute.

## CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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